K062674

5. 510(k) Summary

DEC - 1 2006

Owner's Name & Address:
Diamond Diagnostics Inc
333 Fiske Street
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Randolph Quinn
Development & Compliance Manager
508-429-0450 (x318)

Establishment Registration Number: 3003030793

Date of Preparation: September 1, 2006

Identification of the Device:

Proprietary/Trade name: Mission Trinity B
Common name: blood gas controls with electrolytes, glucose and dyes
Classification name: controls for blood-gases (assayed and un-assayed)
(Classification # 862.1660, Product Code JJY)

Substantial Equivalence Table of Product Part Numbers & Trade Names

Diamond/Mission Product	Bayer Equivalent
DD-96001 Trinity B Level 1	108860 Rapid Complete Level 1
DD-96002 Trinity B Level 2	108868 Rapid Complete Level 2
DD-96003 Trinity B Level 3	108869 Rapid Complete Level 3
DD-96123 Trinity B Levels 1,2,3	Not available

Description of New Device:
Trinity B is a specially formulated, three-level, aqueous material intended for use to monitor all analytes measured by the Bayer line of blood gas, electrolyte, metabolite and CO-Oximetry analyzers. **Trinity B** controls provide a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC as a part of their quality assurance program.
Trinity B contains clinically relevant quantities of pH, PCO2, PO2, sodium, potassium, chloride, ionized calcium, glucose, lactate and suitable concentrations of dyes to simulate clinically relevant values of hemoglobin, and hemoglobin derivatives: O2Hb, COHb, MetHb and HHB.

Intended Use:
Mission Trinity B blood gas, electrolyte, metabolite, CO-Oximeter control is an assayed quality control material used for monitoring the performance of blood gas, electrolyte, metabolite, and CO-Oximeter (Bayer 270/800/400 series) instrumentation for the analytes listed on the Expected Values Chart.

Comparison of Technological Characteristics with Predicate Device:

Characteristics	Mission Trinity B	Bayer Rapid Complete
PN	DD-96001, 96002, 96003, 96123	108860, 108868, 108869
Contents: Any Level	Aqueous solution of buffers, electrolytes, glucose, lactate, dyes, equilibrated with CO2, O2 and N2. Contains NO human or animal materials.	Aqueous solution of buffers, electrolytes, glucose, lactate, dyes, equilibrated with CO2, O2 and N2. Contains NO human or animal materials.
Container	Glass ampule (heat sealed, score break)	Glass ampule (heat sealed, score break)
Color	Red/purple solution	Red/purple solution
Package	30 X 1.8mL (instrument only requires a fraction a of an mL to make a measurement)	30 X 2.5mL
Intended Use	For in-vitro diagnostics use for quality control of pH/Blood Gas analyzers, ISE analyzers, CO-oximeters, and Metabolite analyzers.	For in-vitro diagnostics use for quality control of pH/Blood Gas analyzers, ISE analyzers, CO-oximeters, and Metabolite analyzers.
Storage / Shelf Life	2-8°C (36-months) or 18-25°C 12-months	2-8°C or 18-25°C (until expiration date)

Assessment of Non-Clinical Performance Data:
Tests were conducted to verify specific performance requirements:

- Accelerated (high temperature) stress test to support stability
- Side by side testing of Mission Trinity B vs. Predicate (OEM) product on intended instruments to demonstrate equivalence

Assessment of Clinical Performance Data:
NA

Conclusions:
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Randolph Quinn
Development & Compliance Manager
Diamond Diagnostics Inc.
333 Fiske Street
Holliston, MA 01746

DEC - 1 2006

Re: k062674
Trade/Device Name: Mission Trinity B
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: September 1, 2006
Received: September 8, 2006

Dear Mr. Quinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

4. Indications for Use Statement

510(k) Number (if known): K062674

Device Name: Mission Trinity B

Indications For Use:

Mission Trinity B™ Controls are intended to be used as a quality control material for monitoring the performance of pH, pCO2, pO2, Na+, K+, Ca++, Cl-, glucose, lactate, tHb, %O2Hb, %COHb, %metHb & %HHb on Bayer instrumentation.

For *In Vitro* Diagnostic Use

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K062674